Notice of Allowability	Application No.	Applicant(s)	
	10/730,831	FRANCO, WAYNE P.	
	Examiner	Art Unit	
	Daniel C. Gamett, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *07/05/2006*.

2. ☒ The allowed claim(s) is/are *16,20-24,27 and 28*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *9/26/06* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

David Romeo
DAVID S. ROMEO
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ernest Buff on 9/25/2006.

The application has been amended as follows:

In the claims—

16. A method for the administration of a therapeutic amount of a growth factor protein formulation in the treatment of a patient displaying symptoms of acute coronary artery disease comprising the steps of:

a) administrating by inhalation therapy at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising:

1. a growth factor protein being selected from the group consisting of FGF-1 and FGF-2, and mixtures thereof, and

2. PIGF;

b) monitoring one or more clinical indicators of acute coronary artery disease;

c) determining, based on monitoring the one or more clinical indicators of coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is ~~necessary~~ indicated;

d) depending on the results of the step c), administering one or more additional doses of a second growth factor protein formulation comprising:

1. a growth factor protein being selected from the group consisting of FGF-1 and FGF-2, and mixtures thereof, and

2. PIGF; and

e) repeating steps b) through d) until there is a clinical indication of amelioration of the symptoms of acute coronary artery disease in the patient, or until there is a contraindication to continued treatment.

21. The method of claim 16 wherein the growth factor protein formulation is a liquid aerosol formulation.

24. A method for the administration of a therapeutic amount of a growth factor protein formulation in the treatment of a patient displaying symptoms of chronic coronary artery disease comprising the steps of:

a) administrating by inhalation therapy at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising:

1. a growth factor protein being selected from the group consisting of FGF-1 and FGF-2, and mixtures thereof, and

2. PIGF;

b) monitoring one or more clinical indicators of chronic coronary artery disease;

c) determining, based on monitoring the one or more clinical indicators of chronic coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is ~~necessary~~ indicated;

d) depending on the results of the step c), administering one or more additional doses of a second growth factor protein formulation comprising:

1. a growth factor protein being selected from the group consisting of FGF1 and FGF-2, and mixtures thereof, and

2. PIGF; and

e) repeating steps b) through d) until there is a clinical indication of amelioration of the symptoms of chronic coronary artery disease in the patient, or until there is a contraindication to continued treatment.

28. The method of claim 24 wherein the growth factor protein formulation is a liquid aerosol formulation.

2. The terminal disclaimer filed on 07/05/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6, 759,386 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D.,whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG
Art Unit 1647
27 September 2006

David Romeo
DAVID S. ROMEO
PRIMARY EXAMINER